

AGENDA

NCI Workshop on Criteria for Use of Omics-Based Predictors in Clinical Trials

THURSDAY, JUNE 23

7:30-8:00 REGISTRATION & CONTINENTAL BREAKFAST

8:00-8:15 WELCOME & OPENING REMARKS

Barbara A Conley, MD

8:15-8:30 NCI PERSPECTIVE & OVERVIEW OF GOALS

Lisa M McShane, PhD

8:30-9:10 KEYNOTE ADDRESS

James H Doroshow, MD

9:10 -9:30 WHEN IS A PREDICTOR CLINICALLY USEFUL?

Michael J Birrer, MD PhD

9:30-10:30 PANEL DISCUSSION: CHALLENGES IN SPECIMEN QUALITY AND HANDLING

Organizer & Moderator: David Eberhard, MD PhD

Panelists:

Sunil Badve, MD

Stephen M Hewitt, MD PhD

Andrea L Richardson, MD PhD

Reena Philip, PhD

10:30-10:45 COFFEE BREAK

10:45-11:45 PANEL DISCUSSION: ASSAY CHALLENGES, PITFALLS, AND SOLUTIONS

Organizer & Moderator: Mickey Williams, PhD and William L Bigbee, PhD

Panelists:

Daniel Chan, PhD

Patrick Hurban, PhD

Charles M Perou, PhD

Donna Roscoe, PhD

Leming Shi, PhD

11:45-12:45 LUNCH

12:45-1:05 SAMPLE REUSE IN LARGE SCALE GENE EXPRESSION STUDIES

Paul T Spellman, PhD

1:05-1:25 OVERVIEW OF MODEL BUILDING STRATEGIES AND PERFORMANCE ASSESSMENT METHODS

Jeremy M G Taylor, PhD

1:25-1:40 ASSESSING ANALYTIC REPRODUCIBILITY OF PREDICTIONS

Kevin K Dobbin, PhD

1:40-2:00 BLINDED CLINICAL VALIDATIONS - ROLE OF HONEST BROKER

Michael LeBlanc, PhD

2:00-3:00 PANEL DISCUSSION: DOCUMENTATION, ROBUSTNESS, AND REPRODUCIBILITY OF COMPUTATIONAL MODELS, INCLUDING THE APPROPRIATE SOURCE DATA

Organizer & Moderator: Jill P Mesirov, PhD

Panelists:

Keith Baggerly, PhD

Robert L Becker, MD

Roger Peng, PhD

Paul T Spellman, PhD

Pablo Tamayo, PhD

3:00-3:20 CLINICAL TRIAL DESIGNS FOR EVALUATING OMICS-BASED PREDICTORS

Richard M Simon, DSc

3:20-3:45 REGULATORY REQUIREMENTS

Robert L Becker, MD

Lisa D White, PhD

3:45-4:00 COFFEE BREAK

4:00-5:30 BREAKOUT GROUPS

A. Specimen Issues

B. Assay Issues

C. Model Development, Specification, and Retrospective Performance Evaluation

D. Prospective Phase II and Phase III Clinical Trial Design and Data Stewardship in Clinical Trials

E. Regulatory and Legal Issues

FRIDAY, JUNE 24

7:30-8:00 CONTINENTAL BREAKFAST

8:00-11:35 PRESENTATIONS BY BREAKOUT GROUPS

(25 min. presentation of recommendations +15 min. floor discussion for each group)

8:00-8:40 BREAKOUT GROUP A

8:40-9:20 BREAKOUT GROUP B

9:20-10:00 BREAKOUT GROUP C

10:00-10:15 COFFEE BREAK

10:15-10:55 BREAKOUT GROUP D

10:55-11:35 BREAKOUT GROUP E

11:35-12:00 GENERAL FLOOR DISCUSSION AND WRAP-UP